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Attorney Docket No.: P-2762-US3



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): STEINER, Mitchell S. et al. Examiner: Not yet known

Serial No.: 10/807,517 Group Art Unit: 1614

Filed: March 24, 2004

Title: ISOLATED NUCELIC ACID ENCODING P-HYDE PROTEIN AND METHODS OF INDUCING SUSCEPTIBILITY TO INDUCTION OF CELL DEATH IN CANCER

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO/SB/08:

1. ☒ listing documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents and/or United States patent application publications are not included in this information disclosure statement; and/or
2. ☒ listing documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Serial No. 09/449,817, filed November 26, 1999, which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
3. ☒ listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement;

APPLICANTS: Inventor1\$ inventor2\$  
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Page 2

4. ☐ listing other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a counterpart foreign application, a copy of which is included with this information disclosure statement.

The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

I) ☒ Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits of the subject Application or a request for continued examination thereof, whichever event occurs last pursuant to of 37 C.F.R §1.97 (b); or

II) ☐ After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;

1. ☐ the undersigned hereby states that each item of information listed on the Form PTO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual

designated in §1.56(c) more than three (3) months prior to the filing of this information disclosure statement; or

2. ☐ the undersigned hereby authorizes the Patent Office to charge the fee in the amount of \$180.00 under 37 C.F.R §1.17 (p) to Deposit Account 50-3355.

III) ☐ After the period in (I) and (II) but before the payment of the issue fee and,

1. The undersigned hereby states:

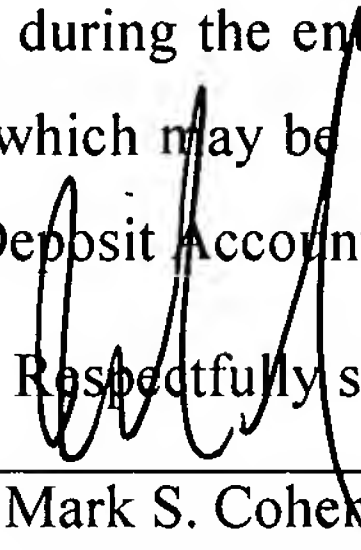
a) ☐ that each item of information cited on the form PTO-1449 was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement; or

b) ☐ that no items of information contained in Form PTO-1449 was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and

2. ☐ The undersigned hereby authorizes the Patent Office to charge the Petition fee in the Amount of \$180.00 under 37 C.F.R §1.17 (p) to Deposit Account 50-3355.

**Except** for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-3355.

Respectfully submitted,

  
Mark S. Cohen  
Attorney/Agent for Applicant(s)  
Registration No. 42,425

Dated: August 20, 2007

**Pearl Cohen Zedek Latzer, LLP**  
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<b>Substitute for form 1449B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/807,517
				Filing Date	March 24, 2004
				First Named Inventor	STEINER, Mitchell S.
				Group Art Unit	1614
				Examiner Name	Not Yet Known
Sheet	2	of	5	Attorney Docket Number	P-2762-US3

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	Q	M.WEIL, M.D. ET AL (1996) "Constitutive Expression of the Machinery for Programmed Cell Death" Journal of Cell Biology, Volume 133, Number 5, June 1996 1053-1059	<input type="checkbox"/>
	R	ELISHEVA YONISH-ROUACH ET AL (1991) "Wild-type p53 induces apoptosis of myeloid leukaemic cells that is inhibited by interleukin-6" Letters to Nature, Vol. 352	<input type="checkbox"/>
	S	STUART H. YUSPA ET AL. "Chemical Carcinogenesis: From Animal Models to Molecular Models in One Decade" Advances in Cancer Research Vol. 50	<input type="checkbox"/>
	T	RENU WADHWA ET AL. (1995) "Correlation between Complementation Group for Immortality and the Cellular Distribution of Mortalin" Experimental Cell Research 216, 101-106	<input type="checkbox"/>
	U	BERT VOGELSTEIN M.D. ET AL. (1988) "Genetic Alternations During Colorectal-Tumor Development" The New England Journal of Medicine Volume 319, Number 9, September 1, 1998	<input type="checkbox"/>
	V	TEMPLEON, L ET AL. (1196) "Down-Regulation of Wild-Type p53 and Up-Regulation of PCNA by pXP2 gene are Associated with the Partial Correction of NER in the XP-A transfectant." Proc. Of the American Association for Clinical Res. 37, 499, 1996	<input type="checkbox"/>
	W	MITCHELL S. STEINER ET AL. (1995) "Molecular Insights into Altered Cell Cycle Regulation and Genitouinary Malignancy" Urol Oncol 1995: 1:3-7	<input type="checkbox"/>
	X	MITCHELL S. STEINER ET AL. (1992) "Transforming Growth Factor-β1 Overproduction in Prostate Cancer: Effects on Growth in Vivo and In Vitro" The Endocrine Society 1992	<input type="checkbox"/>
	Y	EDWIN SILVERBER, BS. (1987) "Statistical and Epidemiologic Data on Urologic Cancer" Department of Epidemiology and Statistics, Department of Research, American Cancer Society, New York Feb 6, 1987	<input type="checkbox"/>
	Z	PETER G. SHIELDS, MD ET AL (1991) "Molecular Epidemiology and the Genetics of Environmental Cancer" JAMA 1991: 266:681-687)	<input type="checkbox"/>
	AA	CHARLES J.SHERR (1993) "Mammalian G <sub>1</sub> Cyclins" Cell, Vol. 73, 1059-1065, June 18, 1993	<input type="checkbox"/>

Examiner Signature		Date Considered	
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\* **EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<b>Sheet</b>	<b>3</b>	<b>of</b>	<b>5</b>	<b>Attorney Docket Number</b>	<b>P-2762-US3</b>

<b>OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS</b>			
<b>Examiner Initials*</b>	<b>Cite No.<sup>1</sup></b>	<b>Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.</b>	<b>T<sup>2</sup></b>
	BB	AUGUSTINUS RINALDY ET AL (1990) "Increased UV Resistance in Xeroderma Pigmentosum Group A Cells after Transformation with a Human Genomic DNA Clone" Proc. Natl. Acad. Sci. USA Vol. 87 pp. 6818-6822, September 1990	<input type="checkbox"/>
	CC	AUGUSTINUS RINALDY ET AL. (1988) "Laboratory Methods, Gene Cloning Using cDNA Libraries in a Differential Competition Hybridization Strategy; Application to Cloning XP-A Related Genes" DNA Volume 7, Number 8, 1988, Mary Ann Liebert, Inc., Publishers pp. 563-470	<input type="checkbox"/>
	DD	DAN MICHALOVITZ ET AL. (1990) "Conditional Inhibition of Transformation and of Cell Proliferation by a Temperature-Sensitive Mutant of p53" Department of Chemical Immunology, Cell, Vol 62, 671-680, August 24, 1990	<input type="checkbox"/>
	EE	KILLIAN MELLON ET AL. (1992) "p53, c-erbB-2 and the Epidermal Growth Factor Receptor in the Benign and Malignant Prostate" The Journal of Urology Vol. 147, 496-499 February 1992	<input type="checkbox"/>
	FF	TIMOTHY J. MCDONNELL ET AL (1992) "Expression of the Protooncogene bcl-2 in the Prostate and Its Association with Emergence of Androgen-independent Prostate Cancer" Cancer Research 52, 6940-6944, December 15, 1992	<input type="checkbox"/>
	GG	DAWN L. MCLELLAN BSC ET AL (1995) "Hereditary Aspects of Prostate Cancer" Can. Med. Assoc. J, Oct 1, 1995: 153 (7)	<input type="checkbox"/>
	HH	EDWIN H. MCCONKEY "The Fractionation of RNA's by Sucrose Gradient Centrifugation" Isolation and Fractionation of Nucleic Acids	<input type="checkbox"/>
	II	GIORGIO MANGIAROTTI ET AL (1981) "Selection and Analysis of Cloned Developmentally-Regulated Dictyostelium Discoideum Genes by Hybridization-Competition" Nucleic Acid Research Volume 9 Number 4, 1981	<input type="checkbox"/>
	JJ	ROBERT B. AMSON, ET AL (1996) "Isolation of 10 differentially expressed cDNAs in p53-Induced Apoptosis: Activation of the Vertebrate Homologue of the Drosophila Seven in Absentia Gene" Proc. Natl. Acad. Sci. USA 93, 1996	<input type="checkbox"/>
	KK	TERUO IWASAKI ET AL (1995) "Cell-Cycle-Dependent Invasion In Vitro by Rat Ascites Hepatoma Cells" Publication of the International Union Against Cancer, Int. J. Cancer: 63, 282-287 (1995)	<input type="checkbox"/>
	LL	JOHN T. ISAACS, ET AL. (1982) "Genetic Instability Coupled to Clonal Selection as a Mechanism for Tumor Progression in the Dunning R-3327 Rat Prostatic Adenocarcinoma System" Cancer Research 42, 2353-2361, June 1982	<input type="checkbox"/>

<b>Examiner Signature</b>		<b>Date Considered</b>	
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	MM	JOHN T. ISAACS, ET AL (1986) "Establishment and Characterization of Seven Dunning Rat Prostatic Cancer Cell Lines and Their Use in Developing Methods for Predicting Metastatic Abilities of Prostatic Cancers" The Prostate 9: 261-281 (1986)	<input type="checkbox"/>
	NN	WILLIAM B. ISAACS, ET AL (1991) "Wild-Type p53 Suppresses Growth of human Prostate Cancer Cells Containing Mutant p53 Alleles" Cancer Research 51: 4716-4720, September 1, 1991	<input type="checkbox"/>
	OO	MAKOTO INABA, ET AL (1996) "Reduced Activity of Anabolizing Enzymes in 5-Fluorouracil-resistant Human Stomach Cancer Cells" JPN. J. Cancer Res. 87, 212-220, February 1996	<input type="checkbox"/>
	PP	HOWARD K. GERSHENFELD, ET AL (1986) "Cloning of a cDNA for a T Cell-Specific Serine Protease from a Cytotoxic T Lymphocyte" Science, Volume 232, 16 May 1996	<input type="checkbox"/>
	QQ	R.E.K. FOURNIER, ET AL (1977) "Microcell-Mediated Transfer of Murine Chromosomes into Mouse, Chinese Hamster, and Human Somatic Cells" Proc. Natl. Acad. Sci. USA, Vol. 74, No. 1. pp. 319-323- January 1977 Genetics	<input type="checkbox"/>
	RR	WAFIK S EL-DEIRY, ET AL (1994) "WAF1/CIP1 is Induced in p53-mediated G <sub>1</sub> Arrest and Apoptosis <sup>1</sup> " Cancer Research 54, 1169-1174, March 1, 1994	<input type="checkbox"/>
	SS	PETER J. EFFERT, ET AL (1992) "Alterations of the P53 Gene are Associated with the Progression of a Human Prostate Carcinoma" The Journal of Urology Vol. 147, 789-793, March 1992	<input type="checkbox"/>
	TT	BOB S. CARTER (1992) "Mendelian Inheritance of Familial Prostate Cancer" Proc. Natl. Acad. Sci. USA Vol. 89. pp. 3367-3371, April 1992	<input type="checkbox"/>
	UU	H. BALLENTINE CARTER, ET AL (1990) "Clinical Evidence for and Implications of the Multistep Development of Prostate Cancer" The Journal of Urology Vol. 143, April 1990.	<input type="checkbox"/>
	VV	SHUBHA ANAND, ET AL (1995) "Induction of Apoptosis in Chronic Myelogenous Leukemia Lymphocytes by Hydroxyurea and Adriamycin" Cancer Letters 88 (1995) 101-105	<input type="checkbox"/>
	WW	Hiller, et al (1995) "y194c03.r1 Soares placenta Nb2HP Homo sapiens cDNA clone IMAGE: 146684 5', mRNA sequence." GenBank Accession Number R80991.	<input type="checkbox"/>

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	XX	GenBank Accession Number AY029585 (2001) "Homo Sapiens dudulin 2 mRNA, complete cds. 1845 bp mRNA."	<input type="checkbox"/>
	YY	Rinaldy, et al (2000) "Role of pHyde novel gene product as an intrinsic factor for apoptotic pathway in prostate cancer." Gan To Kagaki Ryoho Suppl 2:215-22	<input type="checkbox"/>
	ZZ	Steiner, et al (2000) "Growth inhibition of prostate cancer by an adenovirus expressing a novel tumor suppressor gene, pHyde." Cancer Res 60:4419-25	<input type="checkbox"/>
	a	Zhang, et al (2001) "Apoptosis induction in prostate cancer cells in a novel gene product, pHyde, involves caspase-3. Oncogene 200 42:5982-90.	<input type="checkbox"/>
	b	GeneBank Accession Number AAL78206, tumor suppressor pHyde [Homom Sapiens], published February/2002.	<input type="checkbox"/>
	c	Passer, et al (2003) "The p53 inducible TSAP6 gene product regulated apoptosis and the cell cycle and interacts with Nix and the Myt1 kinase." PNAS 2284-2289.	<input type="checkbox"/>
	d	Porkka, et al (2003) "Human pHyde is not a Classical Tumor Supressor Gene in Prostate Cancer. Int. J. Cancer 72-735	<input type="checkbox"/>
	e	Database EMBL Online (2000) " Homo Sapiens cDNA FLJ10829 fis, clone NT2RP4001138" Database Accession Number AK001691	<input type="checkbox"/>
	f	Amson, et al (1996) "Isolation of 10 Differentially Expressed cDNAS in P-53 induced Apoptosis: Activation of the Vertebrate Homologue of the Drosphila Seven In Absentia Gene" Proceedings of the National Acady of Sciences of USA Vol. 93, no.9:3953-3957	<input type="checkbox"/>
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